

## **PACE Program Agreement**

AGREEMENT No. HXXXX

An Agreement Between

The Secretary of the Department of Health and Human Services, who has delegated authority to the Administrator of the Centers for Medicare and Medicaid Services, hereinafter referred to as CMS, and \_\_\_\_\_, the State Administering Agency, hereinafter referred to as SAA,

and

\_\_\_\_\_ hereinafter referred to as the PACE Organization

The Secretary, in finding the PACE Organization to be an eligible organization by the Administrator of CMS and \_\_\_\_\_ State Agency \_\_\_\_\_, agrees to the following with the PACE Organization for the purposes of enacting sections 1894 and 1934 of the Social Security Act:

### **ARTICLE I**

#### **TERM OF AGREEMENT**

**[\$460.32(a)(3)] ; [\$460.34]**

This Agreement is effective for the contract year beginning XXXXXXX through XXXXXXX and may be extended for subsequent contract years in the absence of a notice by a party (CMS, SAA, or the PACE Organization) to terminate the agreement. This agreement supersedes any previous understanding, agreement, arrangement or contract with respect to the provision of and/or the payment for PACE services. This Agreement is subject to termination as contained in Article IV.

The PACE Organization agrees to comply with all regulations or general instructions or other terms and conditions as CMS or the SAA may find necessary and appropriate from time to time for the administration of the PACE program.

### **ARTICLE II**

#### **GENERAL CONDITIONS**

##### **A. Governing Body** **[\$460.32(a)(4)] ; [\$460.62] ; [\$460.60]**

- (1).** The name and telephone number of the PACE Organization's program director and the names of all members of the governing body, and the name and phone number of a governing body member who will serve as a liaison between the governing body and CMS and the SAA is contained in **Appendix A.**

- (2). Any changes in names or telephone numbers shall be reported to CMS and to the SAA prior to the effective date of the change(s).

**B. PACE Structure [§460.32(a)(4)] ; [§460.60]**

- (1). A description of the organizational structure of the PACE Organization, including the relationship to, at a minimum, the governing body, program director, medical director, and to any parent, affiliate or subsidiary entity is shown in **Appendix B**.
- (2). A PACE Organization planning a change in organizational structure shall notify CMS and the SAA, in writing, at least 60 days before the change takes effect.

**C. Service Area and PACE Site(s) [§460.32(a)(1)]**

- (1). The PACE Organization shall furnish PACE services only to participants who live within the designated service area, approved by the SAA and CMS (except as provided in §460.70(b)(2)), which is identified by zip code, county, perimeter street boundaries, census tract, block, or tribal jurisdictional area (as applicable).
- (2). The PACE Organization shall identify the sites at which it will perform PACE services. Any changes in the designated service area and/or the site(s) identified in this agreement must be approved by CMS and the SAA prior to effecting such changes. The designated service area and site(s) are included in **Appendix C**.

**D. Participant Bill of Rights [§460.32(a)(5)]; [§460.110 and §460.112]**

The PACE Organization shall make available to all enrollees a list and explanation of the rights to which they are entitled. The PACE Organization shall assure that those rights and protections are provided. The participant Bill of Rights that will be used to satisfy this requirement is included in **Appendix D**.

**E. Services [§460.32(a)(8)] ; §460.92 and §460.94]**

The PACE Organization agrees to make available comprehensive health care services that include, at a minimum, all services required by 42 CFR §460.92 and 42 CFR §460.94.

**F. Eligibility, Enrollment and Disenrollment [§460.32(a)(7) & §460.32(b)(1)]; [§460.150] [§460.160(b)(3)(ii)]; [§460.162]; [§460.164]**

- (1). The PACE Organization shall consider for enrollment and enroll only those persons who: are 55 years or older, are determined by the SAA to need the level of care required under the State Medicaid plan for coverage of nursing facility services, are able to live in a community setting without jeopardizing their health or safety, and reside in the organization's approved designated service area.
- (2). The PACE Organization's eligibility and enrollment policies, including the criteria used to determine if persons are able to live in a community setting

without jeopardizing their health or safety, is contained in **Appendix E**.

- (3). The SAA, in consultation with the PACE Organization, makes a determination of continued eligibility based on a review of the participant's medical record and plan of care. The criteria used to make the determination of continued eligibility are contained in **Appendix E**.
- (4). The PACE Organization may establish other enrollment criteria in addition to that found in Article II F(1) of this Agreement that support decisions to not enroll persons because of certain circumstances. This criteria, however, shall not modify the criteria in Article II F(1) above. All additional enrollment criteria, if any, are specified in **Appendix F**.
- (5). The PACE Organization agrees that any participant, for any reason, may voluntarily disenroll and, upon doing so, is not liable for any additional or penalty payments. The voluntary disenrollment policy is contained in **Appendix G**.
- (6). The PACE Organization may not involuntarily disenroll a participant except for specific causes. The PACE Organization's involuntary disenrollment policy is located in **Appendix H**.

**G. Grievance and Appeals [§460.32(a)(6)]; [§460.122]; [§460.124]**

- (1). All participants are afforded the right to grieve a PACE Organization's medical and non-medical decisions. They also have the right to appeal the PACE Organization's refusal to provide a particular care-related service or its decision not to pay for a service received by a PACE participant. Internal grievance and appeal procedures for participants are contained in **Appendix I**.
- (2). PACE participants will be informed, in writing, of his or her appeal rights under Medicare or Medicaid managed care, or both. PACE participants will be assisted in choosing which to pursue if both are applicable. The additional appeal rights procedures under Medicare or Medicaid are contained in **Appendix J**.

**H. Quality Assessment and Performance Improvement [§460.32(a)(9), (a)(10), (a)(11)]; [§460.130, §460.134(c), §460.136, §460.140]; [§460.202(b)]**

- (1). A description of the PACE Organization's quality assessment and performance improvement program is contained in **Appendix K**.
- (2). The PACE organization shall meet or exceed minimum levels of performance on standardized quality measures as established by CMS and the SAA. The minimum level of performance is: The organization will achieve an immunization rate for both influenza and pneumococcal vaccinations of 80% for the participant population that is appropriate. (Rate will exclude those participants who have had prior immunization or the vaccine is medically contraindicated).
- (3). The PACE Organization shall furnish data and information on participant care activities, as established by CMS and the SAA. These data are contained in **Appendix L**.

**I. Data Collection and Reporting Requirements [§460.200(a)(b)(c) and §460.204]; [§460.70]**

- (1). The PACE Organization shall collect data, maintain records and submit reports as required by CMS and the SAA. The PACE Organization shall allow CMS and the SAA access to data and records including, but not limited to, participant health outcomes data, financial books and records, medical records, personnel records, any aspect of services furnished, reconciliation of participants, benefit liabilities and determination of Medicare and Medicaid amounts payable.
- (2). The PACE Organization agrees to require that all related entities, contractors or subcontractors agree that the SAA, the U.S. Department of Health and Human Services, CMS, or their designee(s) have the right to inspect, evaluate and audit any pertinent contracts, books, documents, papers, and records of any related entity contractor(s) or subcontractor(s) involving transactions related to this Agreement.

**ARTICLE III  
PAYMENT  
[§460.32(a)(12)]**

For each enrolled participant who is Medicare and/or Medicaid eligible, the PACE Organization will be paid a prospective, monthly capitation amount.

**A. For Participants Eligible for Medicare [§460.180]**

- (1). Separate rates are established for Part A and Part B. For a participant entitled to Part A benefits and enrolled under Part B, both the Part A and Part B rates are paid. For a participant who is entitled to Part A benefits but not enrolled under Part B, only the Part A rate is paid. For a participant enrolled under Part B but not entitled to Part A benefits, only the Part B rate is paid.
- (2). The Medicare payment amount is described in **Appendix M**.

**B. For Participants Eligible for Medicaid [§460.182]**

- (1). The monthly capitated Medicaid payment amount is negotiated between the PACE Organization and the SAA. This payment amount is specified in **Appendix M**.
- (2). The SAA shall describe the enrollment/disenrollment reconciliation procedures, to adjust for the difference between the estimated number of participants on which the prospective monthly payment was based and the actual number of participants claimed in that month. The reconciliation method is contained in **Appendix N**.

**ARTICLE IV  
TERMINATION OF THE AGREEMENT  
[§460.32(a)(13)] [§460.50, §460.52, §460.54]**

**A.** CMS or the SAA may terminate this Agreement at any time for cause, including, but

not limited to: uncorrected deficiencies in the quality of care furnished to participants, the PACE Organization's failure to comply substantially with the conditions for a PACE program, or non-compliance with the terms of this Agreement.

- B.** The PACE organization may terminate this agreement after timely notice to CMS, the SAA and the participants. Notifications shall be made as follows: 90 days before termination to CMS and the SAA and 60 days before termination to the participants.
- C.** The PACE Organization's detailed written plan for phase-down, in the event of termination, is included in **Appendix O**.

## **ARTICLE V REQUIREMENTS OF LAWS AND REGULATION [§460.32(a)(2)]**

**A.** The PACE Organization agrees to comply with all applicable Federal, State, and local laws and regulations, including, but not limited to:

- (1).** Sections 1894 and 1934 of the Social Security Act as implemented by regulations at 42 CFR Part 460;
- (2).** Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR Part 84;
- (3).** The Age Discrimination Act of 1975 as implemented by regulations at 45 CFR Part 91;
- (4).** The Americans with Disabilities Act; and
- (5).** Other laws applicable to the receipt of Federal funds.

## **ARTICLE VI CHANGES TO THE PROGRAM AGREEMENT**

The Parties agree that CMS has the authority to incorporate any additional terms agreed upon by all parties or revise any terms of this agreement and its accompanying appendices that:

- (1).** Are subject to periodic readjustment;
- (2).** Are outmoded as a result of an organizational change made by the PACE Organization;
- (3).** Are outmoded as a result of a contractual modification, initiated by a Party; or
- (4).** Is required by a change in applicable Federal, State, or local laws and regulations.

CMS shall provide the PACE Organization and the SAA with a written notification of any revisions made to the program agreement and/or its appendices, along with the revised program agreement pages. Upon notification, the parties shall notify CMS, in writing, of any disagreement with the terms of the revision(s). Absent written notification to CMS that a party disagrees with the terms contained in CMS's notification, revisions shall become effective thirty (30) days after the date of the initial notification to the parties.

## **ARTICLE VII STATE ADMINISTERING AGENCY REQUIREMENTS**

## Compliance and State Monitoring of the PACE Program

The SAA further assures that its responsibilities under section 1934 of the Social Security Act will be met. All relevant provisions are included in the contract with the PACE entities, either as contractor or SAA responsibility. Both scheduled and unscheduled on-site reviews will be conducted by SAA staff.

- A. Readiness Review: The SAA will perform a Readiness Review of the applicant entity that assures the entity has fully developed its policies and procedures, obtained commitments from key staff, developed its solvency plan and has a facility that meets State and Federal requirements at the time of the application, in accordance with Section 460.12(b)(1).
- B. Monitoring During Trial Period: During the trial period, the SAA, in cooperation with CMS, will conduct comprehensive reviews of a PACE organization to ensure compliance with State and Federal requirements.

At the conclusion of the trial period, the SAA, in cooperation with CMS, will continue to conduct reviews of a PACE organization, as appropriate, taking into account the quality of care furnished and the organization's compliance with State and Federal requirements.

- C. Annual Monitoring: The SAA assures that at least annually it will reevaluate whether a participant meets the level of care required under the State Medicaid plan for coverage of nursing facility services. The SAA understands that this determination may be waived if there is no reasonable expectation of improvement or significant change in the participant's conditions because of the severity of a chronic condition or the degree of impairment of functional capacity. The SAA assures that it will make reviews conducted in accordance with Sections 460.190 and 460.192 available to the public upon request.
- D. Monitoring of Corrective Action Plans: The SAA assures it will monitor the effectiveness of corrective actions required to be taken by the PACE organization.

## Enrollment and Disenrollment

- A. A description of the SAA's enrollment process, to include the criteria for deemed continued eligibility for PACE, in accordance with Section 460.160 (b)(3), is contained in **Appendix P**.
- B. A description of the SAA's process for overseeing the PACE Organization's administration of the criteria for determining if a potential PACE enrollee is safe to live in the community is contained in **Appendix Q**.
- C. A description of the information to be provided by the SAA to enrollees, to include information on how beneficiaries access the State's Fair Hearings process, is contained in **Appendix R**.

- D. A description of the SAA's disenrollment process is contained in **Appendix S**.
- E. The SAA assures that before an involuntary disenrollment is effective, it will review and determine in a timely manner that the PACE organization has adequately documented grounds for disenrollment.
- F. In the event a PACE participant disenrolls or is disenrolled from a PACE program, the SAA will work with the PACE organization to assure the participant has access to care during the transitional period.
- G. The SAA assures it will facilitate reinstatement in other Medicaid/Medicare programs after a participant disenrolls.
- H. The SAA assures that the State PACE requirements and State procedures will specify the process for how the PACE organization must submit participant information to the SAA.

#### Marketing

The SAA assures that a process is in place to review PACE marketing materials in compliance with Section 460.82(b)(ii).

#### Decisions that require joint CMS/SAA Authority

- A. Waivers: The SAA will determine whether regulatory waiver requests submitted by PACE organizations will be considered by CMS and will consult with CMS on those requests. Approved waiver requests are described in **Appendix T**.
- B. Service Area Designations: The SAA will consult with CMS on changes proposed by the PACE organization related to service area designation.
- C. Organizational Structure: The SAA will consult with CMS on changes proposed by the PACE organization related to organizational structure.
- D. Sanctions and Terminations: The SAA will consult with CMS on termination and sanctions of the PACE organization.

#### State Licensure Requirements

The SAA assures that Life Safety Code requirements are met for facilities in which the PACE organization furnishes services to PACE participants in accordance with Section 460.72(b), unless CMS determines that a fire and safety code imposed by State law adequately protects participants and staff.

**AGREEMENT No. HXXXX**

In witness whereof, the parties hereby execute this agreement.

### For the PACE Organization

| Printed Name | Title |
|--------------|-------|
|--------------|-------|

Signature

Date \_\_\_\_\_

Address

## For the State

| Printed Name | Title |
|--------------|-------|
|--------------|-------|

Signature

Date \_\_\_\_\_

Address

## For the Centers for Medicare and Medicaid Services

| Printed Name | Title |
|--------------|-------|
|--------------|-------|

Signature

Date \_\_\_\_\_

Address



**PROGRAM AGREEMENT APPENDICES**  
**APPENDIX A: NAMES AND CONTACT LIST**

**1. Name of Program Director:**

**Telephone Number:**

**2. Name of Governing body/Board of Director contact person:**

**Telephone Number:**

**3. Governing body/Board of Directors:**

## **APPENDIX B: ORGANIZATIONAL STRUCTURE**

## **APPENDIX C: SERVICE AREA AND PACE SITE(S)**

- 1. Identify the entire catchment area the PACE program will be covering.**
- 2. Identify the catchment area by zip codes (if the entire county is not included in the service area), and counties or tribal jurisdictional areas (if applicable).**
- 3. LIST THE NAME AND ADDRESS OF EACH PACE SITE(S).**

## **APPENDIX D: PARTICIPANT BILL OF RIGHTS**

**APPENDIX E: ELIGIBILITY AND ENROLLMENT POLICIES; AND CONTINUED  
ELIGIBILITY CRITERIA**

## **APPENDIX F: ADDITIONAL ENROLLMENT CRITERIA**

## **APPENDIX G: VOLUNTARY DISENROLLMENT POLICY**

**APPENDIX H: INVOLUNTARY DISENROLLMENT POLICY APPENDIX I: INTERNAL  
GRIEVANCE AND APPEAL PROCEDURES**



## **APPENDIX J: ADDITIONAL APPEAL RIGHTS UNDER MEDICARE OR MEDICAID**

**APPENDIX K: QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT  
PROGRAM**

## **APPENDIX L. PARTICIPANT DATA**

These data will be reported electronically into the CMS database, known as "HPMS":

### **1) Routine Immunizations:**

**Definition:** PACE participants who received routine immunizations during the reporting year.

**What data will be reported:**

- 1) Number of participants who received the flu immunization this year;
- 2) Number of participants who have received the pneumococcal immunization in the last ten years;
- 3) Total number of participants at the PACE organization.
- 4a) Number of participants not immunized for flu
- 4b) Number of participants not immunized for pneumococcal
- 5) Reason for not immunizing

**Frequency:** During the inoculation time period (e.g. Sept. to Jan.)

**How to use the measure:** Compare the number of PACE participants who were enrolled during the reporting year to the number of participants who received routine immunizations (flu and pneumococcal) during the reporting year.

Minimum levels of Performance: The organization will achieve an immunization rate for both influenza and pneumococcal vaccinations of 80 % for the participant population that is appropriate. (Rate will exclude those participants who have had prior immunization or the vaccine is medically contraindicated).

### **2) Grievances and Appeals**

**Definition:** Grievances are defined as either a written or oral complaints that expresses dissatisfaction with service delivery or the quality of care provided. Appeals are defined as a written complaint for the noncoverage or nonpayment of a service or item.

**What data will be reported:**

1. Total number of participants during the quarter;
2. Total number of grievances filed during the quarter;
3. Total number of appeals filed during the quarter;
4. Source of each grievance or appeal (participant, family, caregiver, etc.);
5. Date of initiation of each grievance or appeal; and
6. Date of resolution of each grievance or appeal.

**Frequency:** Quarterly

**How to use the measure:** Monitor trends and patterns. The actual

number of grievances and appeals alone should not be viewed as an indicator of a problem. The high number of grievances could mean that participants are encouraged to speak up for themselves and voice their concerns.

### **3) Enrollments**

**Definition:** Individuals enrolled in the PACE program by month.

**What data will be reported:** Number of individuals who enrolled in the program.

**Frequency:** Quarterly

**How to use the measure:** Monitor trends and patterns to determine if there are any accessibility issues and to determine if the PACE organization has sufficient financial resources to conduct appropriate marketing activities. This information can also be used to evaluate the PACE organization's ability to maintain an appropriate census.

### **4) Disenrollments**

**Definition:** Participants who disenrolled from the program for reasons other than death.

**What data will be reported:**

1. Total number of participants;
2. Number of voluntary disenrollments;
3. Number of involuntary disenrollments; and
4. Reason for each disenrollment: leaving the service area, failure to pay premium, disruptive or threatening behavior, no longer meets States level of care, program agreement with CMS terminates or not renewed, organization is unable to offer services due to loss of State license, keep personal physician, wishes to access out of network or other.

**Frequency:** Quarterly

**How to use the measure:** Utilize this information to determine if there are any problems with site operations, such as accessibility, provision of services, etc. that are causing voluntary disenrollments. In addition, this information can be used to review the organization's policies on involuntary disenrollments.

## **5) Prospective Enrollees**

**Definition:** Potential participants who were interviewed, met eligibility requirements but did not enroll in the PACE program.

**What data will be reported:**

- 1) Number of potential participants who were interviewed but did not enroll in the PACE program by aggregate reason; and
- 2) Indicate the category that explains the reason each potential participant did not enroll, e.g. not safe to remain in the community, mental health concerns, lack of support network, requiring 24-hour care, preference for own physician, preference for other health care provider or institution, financial reason to avoid share of cost, unwilling to comply with treatment plan, or other with explanation.

**Frequency:** Quarterly

**How to use the measure:** This information can be utilized to determine if the PACE organization is following the appropriate eligibility criteria and to determine if the organization is conducting appropriate marketing activities.

## **6) Readmissions**

**Definition:** PACE participants re-admitted to an acute care hospital (excluding hospitalizations for diagnostic tests) in the last 30 days.

**What data will be reported:**

1. Total number of participants;
2. Total number of participants admitted to the hospital in the last 30 days;
3. Specific reason, including diagnosis, for participant's admission;

**Frequency:** Quarterly

**How to use the measure:** Review those with high usage to determine if intervention by the PACE organization could have prevented some of the hospitalizations. Readmission for the same reason in a 30-day period could indicate that the length of stay is too short or there is inadequate follow-up care by the PACE organization. Conduct quarterly comparisons to get a total picture of the care provided by the organization.

## **7) Emergent (unscheduled) Care**

**Definition:** PACE participants seen in the hospital emergency room (including care from a PACE physician in a hospital emergency department) or an outpatient department/clinic emergency, Surgicenter.

**What data will be reported:**

1. Total number of participants;
2. Total number of participants by (aggregate) same diagnosis and;
3. Specific reason including diagnosis.

**Frequency:** Quarterly

**How to use the measure:** Review those with high usage to determine if intervention by the PACE organization could have prevented some of the visits to the ER.

**8) Unusual Incidents for Participants and the PACE site (to include staff if participant was involved)**

**Definition:** Unanticipated circumstances, occurrences or situations which have the potential for serious consequences for the participants.

**Examples include, but are not limited to:** falls at home or the adult day health center; falls while getting into the van; van accidents other than falls; participant suicide or attempted suicide; staff criminal records; infectious or communicable disease outbreaks; food poisoning; fire or other disasters; participant injury that required follow-up medical treatment; participant injury on equipment; lawsuits; medication errors and any type of restraint use. This is not an inclusive list, so we would expect PACE sites to submit quarterly information on any unanticipated situations that occur.

**What data will be reported:** Number of unusual incidents aggregated by reason

**Frequency:** Quarterly

**How to use the measure:** Analyze categories focusing on whether these incidents were preventable, what steps were taken to resolve the problem, and what changes are being made to improve prevention. Is there a pattern that indicates a need for follow-up to investigate health and safety issues and procedures? Is this a program problem (e.g. negligence by staff) or a participant problem (e.g. verbal outbursts by participant with mental illness or severe dementia)?

**9) Deaths**

**Definition:** Death of participants during the given reporting period.

**What data will be reported:**

1. Number of participants (can be aggregated by reason and setting, if same);
2. Number of deaths;
3. Setting of the participant's death; and
4. Cause of the participant's death.

**Frequency:** Quarterly

**How to use the measure:** Analysis to determine if there is a pattern indicating inappropriate setting for the participant or problems with accessibility to 24 hour care. Because of the link between the number of deaths and enrollment, this information may also indicate if the PACE organization is maintaining an appropriate census to remain fiscally viable.

The data submitted must come exclusively from the PACE organization, not the parent organization.

If the PACE organization has more than one site of care/treatment, each site must be identified separately.

Version: December, 2004

## **APPENDIX M: MEDICARE AND MEDICAID PAYMENT AMOUNTS**

### **Medicare:**

Before January 1, 2004, Medicare payment to PACE organizations is based on the Medicare Part A and Part B demographic aged rate for the county in which the participant lives, adjusted by a factor of 2.39. Beginning January 1, 2004, Medicare payment will transition to a risk adjustment approach. Under this methodology, payment will be based on Part A and Part B county rates that have been restandardized so that we can appropriately apply the national risk adjustment and frailty factors relevant to each participant. The risk/frailty score for community-dwelling participants is based on the CMS - Hierarchical Conditions Category (CMS-HCC) community model used in the Medicare+Choice program, which is based on diagnostic information submitted by PACE organizations, plus an organization-specific frailty score described below.

The PACE organization's frailty score will be based on the responses received from community-dwelling participants on the PACE Health Survey, which identifies participant difficulty in performing activities of daily living (ADLs). The total number of respondents with difficulty in each ADL group will be multiplied by a specified factor. The resulting products are summed and divided by the total number of community-dwelling respondents in order to determine the average frailty of the organization's participants. The organization's frailty score is added to each participant's risk score to determine the total risk/frailty score for that individual participant.

For new organizations, we will determine an average frailty score based on the responses we received from existing PACE organizations. The total number of respondents in all active organizations with difficulty in each ADL group will be multiplied by the specified factor. The resulting products are summed and divided by the total number of community-dwelling respondents in all active organizations in order to determine the average frailty score. The average frailty score is used to establish the risk/frailty score for participants in new PACE organizations. Since frailty scores apply only to community-dwellers, the risk/frailty score for institutionalized participants is the risk score under the CMS risk adjustment (CMS-HCC) institutional model.

For PACE participants who have end-stage renal disease (ESRD), the PACE organization will receive the statewide ESRD rate multiplied by the PACE ESRD frailty factors, i.e., 1.46 for Medicare Part A and 1.36 for Medicare Part B.

A notice providing updates to the PACE Medicare payment methodology is published in the Federal Register each year and is effective for the following calendar year. Information about how to access updates to the PACE Medicare payment methodology will be provided through the PACE LISTSERVE.

### **Medicaid:**



**APPENDIX N: STATE ENROLLMENT/DISENROLLMENT RECONCILIATION  
METHODOLOGY**

## **APPENDIX O: TERMINATION PHASE - DOWN PLAN**

## **APPENDIX P: SAA ENROLLMENT PROCESS**

## **APPENDIX Q: SAA OVERSIGHT OF PO ADMINISTRATION OF SAFETY CRITERIA**

## **APPENDIX R: INFORMATION TO BE PROVIDED BY THE SAA TO ENROLLEES**

## **APPENDIX S: SAA DISENROLLMENT PROCESS**

## **APPENDIX T: REGULATORY WAIVERS**